K071503

JUL 26 2007

ITEM I

510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Syntermed, Inc.
Registration No. 1066019
Owner Operator I.D. 9041128
Device Regulation Number: 892.1200
Product Code: KPS
Classification Panel: Radiology
Voice: (714) 281-1256, FAX: (714) 281-1290
Contact person: Kenneth F. Van Train
Address: Syntermed, Inc.
Tower Place Center
3340 Peachtree Road, NE
Suite 1800
Atlanta, GA 30326
Date Summary Prepared: May 30, 2007

2. Medical Device:

Emory Cardiac Toolbox™ 3.1 - Display and Processing program for gated SPECT & PET myocardial perfusion studies executing on nuclear medicine computer systems and Windows PC's.

Classification Name – System, Tomography, Computed, Emission

3. Medical Device Equivalence:

AutoSPECT Plus developed by ADAC Laboratories K992317 for Emory Reconstruction Toolbox (ERTb™) and GE Vivid 7 Diagnostic Ultrasound System with TSI developed by GE Medical Systems K031663 for Phase Analysis.

4. Device Description:

The Emory Cardiac Toolbox™ 3.1 is used to display gated wall motion and for quantifying parameters of left-ventricular perfusion and function from gated SPECT & PET myocardial perfusion studies. These parameters are: perfusion, ejection fraction, end-diastolic volume, end-systolic volume, myocardial mass, transient ischemic dilatation (TID), and cardiac mechanic dyssynchrony. In addition, the

program offers the capability of providing the following diagnostic information: computer assisted visual scoring, prognostic information, expert system image interpretation, and patient specific 3D coronary overlay. The program can also be used for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface and for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM). The Emory Cardiac Toolbox can be used with any of the following Myocardial SPECT Protocols: Same Day and Two Day Sestamibi, Dual-Isotope (Tc-99m/Tl-201), Tetrofosmin, and Thallium, Rubidium-82, N-13-ammonia, FDG protocols, and user defined normal databases. This program was developed to run in the IDL operating system environment which can be executed on any nuclear medicine computer systems which supports IDL and the Aladdin (General Electric) software development environment. The program processes the studies automatically, however, user verification of output is required and manual processing capability is provided.

5. Intended Use and Potential Adverse Effect on Health:

The intended use of this program was to provide the physician with a program which would allow him to determine quantitative analysis of the myocardial perfusion, display wall motion and determine measurements of ejection fraction and ventricular volumes from his patients gated SPECT & PET myocardial perfusion study, obtain visual interpretation scores, prognostic information, expert system interpretation, for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface, for the assessment of cardiac mechanic dyssynchrony using phase analysis, and for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM). This program serves merely as a display and processing program to aid in the diagnostic interpretation of a patients' study. It was not meant to replace or eliminate the standard visual analysis of the gated SPECT & PET study. The physician should integrate all of the patients' clinical and diagnostic information, i.e. patients' history, stress and/or rest EKG, quality control images, visual interpretation of the gated tomographic images, and quantitative results, prior to making his final interpretation. This comprehensive processing technique (as with all diagnostic imaging) is not perfect, and will be associated with some false positive and false negative results. The expected accuracy of the initial program can be found in the multicenter trial results listed in the article by Vansant et al Emory Cardiac Toolbox™ (CEqual®, EGS™) Version 2.0, Ref. 510(k) #: K992450 and Version 2.1, Ref. 510(k) #: K014033). The accuracy for modifications in version 3.1 for SPECT reconstruction and for evaluation of cardiac mechanic dyssynchrony by phase analysis can be found in Item H (Testing & Validation) of this 510(k) submission. The physician should be aware of the accuracy when integrating the quantitative results for his final interpretation. Therefore, this program has no direct adverse effect on health since the results represent only a part of the information which the

physician will utilize for his final interpretation. The final responsibility for interpretation of the study lies with the physician.

6. Marketing History:

There have been several medical device gated SPECT programs marketed in the past which perform similar functions to those performed by the Emory Cardiac Tool Box™ 2.0, 2.1, and 2.6. These programs are all used for the purpose of displaying wall motion and deriving functional parameters for the diagnostic interpretation by a physician. The Emory Cardiac Tool Box™ 3.1 provides additional features for the assessment of cardiac mechanic dyssynchrony using phase anaylsys, and for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM) which executes in the IDL operating system environment and we believe is substantially equivalent to AutoSPECT Plus developed by ADAC Laboratories K992317 for Emory Reconstruction Toolbox (ERTb™) and GE Vivid 7 Diagnostic Ultrasound System with TSI developed by GE Medical Systems K031663 for Phase Analysis. To our knowledge there have been no safety problems with the AutoSPECT Plus program which has been in the marketplace since October 1, 1999 and with GE Vivid 7 Diagnostic Ultrasound System with TSI which has been which has been in the marketplace since June 9, 2003.

7. Conclusions:

The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and validation. The effectiveness of the initial program, Emory Cardiac Toolbox™ 2.0, has been established in phantom and computer simulations studies, in-house trial validations which included an evaluation of left ventricular functional parameter calculations in 217 patients, and in a multicenter trial validation consisting of 80 patients. In addition, the computer assisted visual scoring, prognosis, expert system, and coronary fusion algorithms were successfully evaluated in 20, 504, 461, and 9 patients respectively. Additional validation of the Emory Cardiac Toolbox™ 2.1 program for development and validation of Rb-82 normal limits (n=176) and validation of PET tools for assessment of perfusion – metabolism match-mismatch (n=90) were successfully completed. Validation for the Emory Cardiac Toolbox™ 2.6 program included development and validation of N-13-ammonia normal limits (n= 144) and validation of the alignment method for 3D CT coronary artery onto the left ventricular 3D epicardial surface using phantom and patient studies (n = 8). Validation for the Emory Cardiac Toolbox™ 3.1 program included development (phantom, animal, and patients n=4) and prospective validation of SPECT reconstruction in 10 patients and for phase analysis which included development in 90 normal patients and prospective validation in 75 additional patients and these results are listed in Item H, Testing & Validation. We contend that the method employed for the development and validation for the assessment of cardiac mechanic dyssynchrony using phase anaylsys, and for generation of the short axis, vertical, and horizontal long axis tomograms from the

SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM), Emory Cardiac Toolbox™ 3.1, have proven its safety and effectiveness. In our opinion the additional features in Emory Cardiac Toolbox™ 3.1 for SPECT reconstruction and phase analysis are substantially equivalent to AutoSPECT Plus developed by ADAC Laboratories K992317 for Emory Reconstruction Toolbox (ERTb™) and GE Vivid 7 Diagnostic Ultrasound System with TSI developed by GE Medical Systems K031663 for Phase Analysis which have both been cleared for marketing. The Emory Cardiac Toolbox™ 3.1 is intended for the same purpose along with the additional purpose of alignment SPECT reconstruction and phase analysis and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 26 2007

Mr. Kenneth F. Van Train
President
Syntermed, Inc.
245 Owens Drive
ANAHEIM CA 92808

Re: K071503
Trade/Device Name: Emory Cardiac Toolbox 3.1
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and LLZ
Dated: May 30, 2007
Received: June 5, 2007

Dear Mr. Van Train:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K071503

Device Name: Emory Cardiac Toolbox 3.1 Executing on Nuclear Medicine Computers

Indications For Use:

The Emory Cardiac Toolbox™ (CEqual®, EGS™) 3.1 software program should be used for the quantification of myocardial perfusion (CEqual®), for the display of wall motion and quantification of left-ventricular function parameters from gated Tc^{99m} SPECT & PET myocardial perfusion studies (EGS™), for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface, for the assessment of cardiac mechanic dyssynchrony using phase anaylsys, and for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071503